1. 510(k) Summary

JAN 1 1 2005 K042870

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

EndoTwinn B.V.
Danzigerkade 17
1013 AP Amsterdam
The Netherlands
Telephone: +31 20 486 7571
Fax: +31 20 486 3280

B. Contact Person

Frank Verhoeven

C. Date Prepared

June 2004

D. Device Name

Trade Name: EndoTwinn
Classification Name: 872.3850 - Gutta Percha accessory
Regulation Number and Product Code: 872.3850, EKM
Classification Panel: Dental

E. Device Description

The device is a battery-operated dental instrument heater which is designed to provide continuous heat and/or vibration at the tip of a dental instrument. The low frequency vibration stimulates the transformation of gutta percha in a solid mass. The temperature is regulated by the type of tip attached to the handpiece and it automatically maintains a preset temperature for consistent results. The cordless handpiece is easily operated by a single button and can be recharged by placing the handpiece in a charger. The tips are autoclavable and the handpiece can be disinfect with 80% alcohol.

F. Intended Use

The intended use of the dental instrument heater – The EndoTwinn - is to provide continuous heat and/or vibration at the tip of a dental instrument. The EndoTwinn is designed for processing gutta percha (cutting softening, spreading, compacting) and cutting plastic handles of obturators during a root canal treatment The device may only be operated by dentists and endodontists.

G. Substantial Equivalence

The dental instrument heater is substantially equivalent to several other legally marketed devices in the United States. The dental instrument heater marketed by Sybron functions in a manner similar to and is intended for the same use as the EndoTwinn.
Predicate Devices:

- Sybron, System B (K970715) HeatSource
- Sybron, Touch 'n Heat (K963862)

H. Device Testing Results and Conclusion

The devise is tested thoroughly and it complies to the standards for this class II a medical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2005

Endo Twinn B.V.
C/O Mr. J.A. Van Vugt
Responsible Third Party Official
Kema Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K042870
Trade/Device Name: Endo Twinn
Regulation Number: 872.3850
Regulation Name: Gutta Percha
Regulatory Class: I
Product Code: EKM
Dated: December 28, 2004
Received: December 30, 2004

Dear Mr. Vugt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: (unknown)

Device Name: EndoTwinn

Indications for Use:

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Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: NO (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042870